



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 17 1998

Mr. Brian Kunst  
Vice President, Regulatory Affairs and Quality Assurance  
AngioDynamics, Inc.  
603 Queensbury Avenue  
Queensbury, NY 12804

Re: K971314  
Trade Names: Dialysis-Crossed Aspiration Thrombectomy (DCAT)  
Catheter System and Cohn Thrombectomy Catheter  
Regulatory Class: II (two)  
Product Code: DXE  
Dated: December 15, 1997  
Received: December 17, 1997

Dear Mr. Kunst:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

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response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, reading "Thomas J. Callahan". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Thomas J. Callahan, Ph.D.  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K971314

Device Name: ANGIODYNAMICS, Inc. DCAT Thrombectomy Catheter System

Indications For Use:

The ANGIODYNAMICS, Inc. DCAT System is for the percutaneous isolation and aspiration of fresh thrombus from vessels in the vascular system. Additionally, it may also be used for temporary occlusion of blood vessels, isolated infusion of fluids, and blood sampling.

Device Name: ANGIODYNAMICS, Inc. Cohn Thrombectomy Catheter

Indications For Use:

The ANGIODYNAMICS, Inc. Cohn Thrombectomy Catheter is intended to be used for temporary occlusion and removal of thromboemboli from native or synthetic vessels within the arterial circulation.



(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K971314

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

or

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

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